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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,468	08/31/2006	John S. Yu	67789-089US0	5815

50670 7590 10/27/2010

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EXAMINER	
MACFARLANE, STACEY NEE	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
10/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,468	YU ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-11,13,16,18,22-32,34-36 and 38* is/are pending in the application.

4a) Of the above claim(s) *4,10,11,13,16,18 and 22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-9, 34-36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 2, 3, 14, 15, 19-21 and 39-43 are cancelled; Claims 1, 2, 13, 18, 22, 34, have been amended as requested in the amendment filed on December 23, 2009. Following the amendment, claims 1, 4-11, 13, 16, 18, 22-32, 34-36 and 38 are pending in the instant application.

Claims 4, 10, 11, 13, 16, 18 and 22-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 5-9, 34-36 and 38 are under examination in the instant office action.

Claim Rejections - 35 USC § 102/103 (New Necessitated by Amendment)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. As currently amended, Claims 1, 5-9, 34-36 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious

over Luo et al., Journal of Neurochemistry, 83:1481-1497, 2002, as evidenced by Markagakis et al., Glia, 45:133-143, 5 November 2003.

The combined teachings of the references demonstrate that there are subpopulations of neural stem cells, and a continuum of differentiation as cells progress from pluripotent neural stem cell to glial-restricted precursor to human astroglial progenitor.

Luo et al. teach stem cells isolated from the neural tube or neuroepithelium, can be divided into A2B5+ glial-restricted progenitor cells and NCAM+ neuron-restricted progenitors. Luo et al. teach that both CXCR4 and SDF-1 genes are expressed in only in the A2B5 positive glial-restricted progenitor cells (Table 3).

With regards to expression the instant specification acknowledges differential expression along the continuum of glial differentiation. Paragraph [0061] states: "A2B5 and embryonic form of neural cell surface molecule (E-NCAM), indicative of NSC that have initiated differentiation pathways towards astrocytic and neuronal fates, respectively; GFAP, expressed in cells of astroglial lineages; excitatory amino acid transporter genes (EAAT1 and EAAT2), glutamate transporter related proteins found in functional, differentiated astroglial cells". (*emphasis added*)

The Luo et al. reference teaches that neural tube stem cells also do not express many genes often found in differentiated glia (Table 1, "not detected"), but the Luo et al. is silent with respect to specific expression of EAAT1 or EAAT2. The Maragakis et al. art, however, is relied upon as evidence that it was well-known within the art that glial-restricted progenitor cells differentially express EAAT1 as they progress along the

continuum from glial precursor to astrocyte precursor to differentiated astrocyte. The Maragakis et al. art teaches that EAAT2 is not expressed in *any* of these precursors (Abstract and Figure 2B). EAAT1 expression is only detected upon a shift along the astrocyte lineage (Figure 2A and page 138, paragraph bridging columns), which also corresponds to the expression of sodium-dependent glutamate uptake activity (Figure 4) and correlates with increased mitotic activity (page 140, column 2, first and second paragraphs).

As previously stated, the instant claims are drawn to product-by-process, namely, an isolated neural stem cell. The cells are selected by their biomarker properties but Product-by-Process Claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The courts have stated, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113.

Examiner maintains that the cells described within the Luo et al. prior art are indistinguishable from those of the instant claims. That the Luo et al. reference did not specifically assay for EAAT1 or EAAT2 expression is moot as the preponderance of evidence within the art and within the instant disclosure, teaches that EAAT1 expression occurs upon astroglial differentiation.

Where Applicant has claimed a composition of matter in terms of a property or characteristic and the composition of the prior art is substantially identical in structure or composition but the characteristic is not explicitly disclosed by the reference, a *prima facie* case of either anticipation or obviousness has been established and the burden of proof rests upon the Applicant to demonstrate that the prior art does not necessarily or inherently possess the characteristics of Applicant's claimed product. Contrary to Applicants arguments made on page 9 of Remarks filed 12/23/2009, the Examiner does not need to provide evidence of inherency, once the Examiner presents "reasoning tending to show inherency, the burden shifts to the Applicant to show an unobvious difference"; "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." *In re Bes*t, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977).

Therefore, claims 1, 5-9, 34-36 and 38 are rejected.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/Jeffrey Stucker/
Supervisory Patent Examiner, Art Unit 1649